REMARKS

Reconsideration and withdrawal of the rejections of this application are requested in view of the amendments and following remarks, which are believed to place the application in condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1-6, 9, 10, 13 and 16-21 are under consideration. Claims 1-6, 9, 10, 13 and 16-18 have been amended; claims 19-21 have been added; claims 7 and 8 have been cancelled.

No new matter is added. Support for the amended claims is found throughout the specification.

It is submitted that these claims are patentably distinct from the references cited by the Examiner, and that these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments of the claims herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but rather the amendments are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Furthermore, it is explicitly stated that the herewith amendments should not give rise to any estoppel, as the herewith amendments are not narrowing amendments.

II. THE REJECTION UNDER 35 U.S.C. §112, 1ST PARAGRAPH, IS OVERCOME

Claims 1-10 and 13 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement. The rejection is traversed.

The Office Action alleges that the claimed invention is enabled only for a method of producing an infectious retrovirus comprising an amphotropic envelope. To the contrary, the claimed invention is applicable to numerous viral envelopes. On page 10 of the specification, a representative number of endogenous receptors and viral envelopes are listed, and interference of the binding of amphotropic envelope to the pit2 receptor is taught in Example 6. The same ribozyme sequence would be applicable for enhancing a production system employing a FeLV envelope, for example. In addition, it would be within the routine skill of the ordinary artisan to generate sequences that would bind to other receptors on other cell types, particularly since the methodology for generating sequences capable of inhibiting receptor expression is taught on pages 11-14 of the instant application.

To support the enablement rejection, the Office Action cites the specification at page 21, which reports that 293T producer cells do not express an endogenous receptor for ecotropic envelope. It is well known that 293T cells are not the only producer cells available for use in production systems for packaging of retroviral genomes; and, it is noted in the specification (page 9, lines 4-14) that producer cells of any suitable cell type can be used. Producer cells may be derived from mammalian species other than human, *e.g.*, canine, equine, and murine cell lines. The specification, *e.g.*, at Table 4 (page 20) and on page 21, reports the fact that ecotropic envelopes are incapable of infecting human cells because of a lack of the appropriate endogenous receptors. This was well known in the art at the time the instant application was filed. See RNA Tumor Viruses, Molecular Biology of Tumor Viruses, Second Edition 1/Text, 1984 at page 35 and Table 2.6 on page 74 (copy of relevant pages attached). While the appropriate receptors for ecotropic envelopes are not found on human cells, they are found on mouse cells and the claimed invention applies accordingly. Specifically, the claim language requires the producer cell to have "an endogenous receptor which is capable of binding to the envelope polypeptide", and thus, an ecotropic envelope would be excluded from the claim if the producer cell is a 293T cell.

The Office Action cites Kurre *et al.*, as representative of the state of the art, and states that it conflicts with the claimed invention. Contrary to this assertion, the teachings of Kurre *et al.* actually support the instant invention. Kurre *et al.* report on retroviral transduction of target cells, and not a retroviral production system, however, the teachings of Kurre *et al.* teach that over-expressing the pit2 receptor increases infectivity of a rat target cell. The instant application teaches that, by blocking the interaction between the endogenous receptor and the envelope used for pseudotyping a candidate retroviral vector, infectivity is inhibited, thereby increasing titer and enhancing retroviral production. Therefore, more receptor facilitates more efficient transduction of a target cell (Kurre *et al.*), while less receptor facilitates more efficient production of a candidate retroviral particle (instant invention). In retroviral production, less infection results in more retroviral vector, and the present inventors were the first to exploit this by inhibiting the envelope-receptor interaction to enhance retroviral production technology. Therefore, the teachings of Kurre *et al.* and the current application are consistent.

Reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph are requested.

III. THE REJECTIONS UNDER 35 U.S.C. §112, 2ND PARAGRAPH, ARE OVERCOME

Claims 1-10, 13, 16 and 18 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite.

The Office Action objected to the term "enhancing the production" in claim 1, as there was no comparative basis for "enhancing". Claim 1 has been amended for clarity and, support can be found in Example 6.

The Office Action alleged that "effecting the cleavage" in claims 4 and 18 was unclear. This language has been removed from claims 4 and 18, and the subject matter has been re-presented in new claims 19 and 21. It is believed that the language of the new claims clarifies the embodiment relating to cleavage of the nucleotide sequence.

Consequently, the §112, second paragraph, rejections are overcome, and reconsideration and withdrawal are requested.

IV. THE REJECTION UNDER 35 U.S.C. §102 IS OVERCOME

Claims 16 and 17 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Combadiere *et al.* The rejection is traversed.

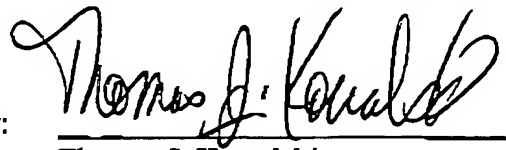
In order to be a proper Section 102 rejection, the prior art reference must contain all of the elements of the claimed invention. *See Lewmar Marine Inc. v. Barient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Contrary to the assertions in the Office Action, each element of the claimed invention is not taught by Combadiere *et al.* For example, Combadiere *et al.* do not teach a retroviral "producer cell", *i.e.*, a producer cell comprising an infectious retrovirus having an envelope polypeptide, as is required by the claims. A producer cell is a cell comprising all the elements necessary for the production of an infectious retroviral vector, *i.e.*, gag/pol, a packaging signal, env, and a genome. See pages 7-9 of specification. The Office Action cites pages 16-17 of Combadiere *et al.* as disclosing cell lines; however, neither there nor elsewhere within the text of this cited reference is there a teaching relating to a producer cell as claimed.

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §102(a) are requested.

CONCLUSION

In view of these amendments and remarks herewith, the application is believed to be in condition for allowance. Early and favorable reconsideration of the application, reconsideration and withdrawal of the rejections, and prompt issuance of a Notice of Allowance are earnestly solicited. The Commissioner is authorized to charge any fee occasioned by this paper, or credit any overpayment of such fees, to Deposit Account No. 50-0320.

Respectfully submitted,
FROMMER LAWRENCE & HAUG LLP

By: 

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